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Therapeutic drug monitoring of atazanavir in pregnancy

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Purpose of the study

Achieving and maintaining an optimal plasma concentration of antiretroviral drugs is essential for minimising the risks of mother-to-child transmission of HIV. However, altered pharmacokinetics during pregnancy means there is a real risk of both under- and over-dosing of medications. The aim of this study is to describe atazanavir/ritonavir (ATV/r) pharmacokinetics during pregnancy.

Methods

Pregnant HIV-positive women receiving ATV/r as part of their routine prenatal care were prospectively enrolled in this open labelled study. Plasma concentrations were determined in the first (T1), second (T2) and third (T3) trimester. Post-partum sampling was performed where applicable. High-performance liquid chromatography (HPLC), with a limit of quantification of 250 ng/ml, was used to measure ATV/r concentrations.

Summary of results

From January 2007, 14 women were enrolled in the study. All received ATV/r at standard dose of one tablet once a day. 5/14 women were started on ATV/r during pregnancy. The median gestation at initiation was 24 weeks (range 13 to 25 weeks). Nine women were on HAART prior to pregnancy, six of whom were virally suppressed on enrolment in the study. Median baseline CD4 count was 367 (range 176 to 869). Median baseline viral load was <50 cpm (range <50 to 23,544). 11/14 were black African and the average age was 31 years (range 26 to 34).

TDM was drawn in 5/14 in T1; 7/14 in T2; 8/14 in T3 and 3/14 PP (≤ 12 weeks). Most samples tested were above the MEC of 150 ng/ml with values ranging between 472 ng/ml (T2 sample) and 3,400 ng/ml (T1 sample). 2/23 samples were below the lower limit of quantification (62 ng/ml). There was no correlation between TDM levels and viral load.

Conclusion

ATV/r concentrations showed a considerable degree of inter-patient variability in our sample. However, the standard dose did achieve therapeutic levels both antepartum and post-partum in the majority of cases, suggesting the current regimen is appropriate in pregnancy.

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